Section 5

PERIODIC SERVICE & TECHNICAL SPECIFICATIONS

PERIODIC SERVICE

The manufacturer recommends that the VAPR Generator be regularly inspected to ensure continued safety of operation throughout its service life. The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge and practical experience to perform such tests.

- Inspect the Generator and the Footswitch for obvious signs of mechanical damage or wear. Ensure that the Generator case shows no sign of tampering. There are no user serviceable items within the Generator or Footswitch.
- Check that the Generator back panel label is present and decipherable and that the front panel markings and symbols are still legible.
- Retract the fuse drawer of the mains inlet connector and verify that both fuses are intact and match the rated current and breaking characteristics as per the back panel label.
- Verify that the resistance between the earth terminal of the mains inlet connector and the Generator enclosure is within the limits defined in IEC 601-1 or the corresponding national standard as applicable.
- Switch on the Generator ensuring that the initial internal self-test completes normally as reported on the front panel display. Check that the audio alarm, front panel warning indicator and vacuum fluorescent display are functioning normally via the user verification sequence which follows initialization.
- Check that the enclosure earth leakage current is within the limits for Class I equipment as prescribed with IEC 601-1 or the corresponding national standard as appropriate.
- Measure the patient earth leakage currents and ensure it is within the limits of BF type equipment as defined within IEC 601-1 or a corresponding national standard.
- Details of these tests should be recorded in an equipment log with the date of test for future reference. Contact Mitek customer service should a unit fault be suspected.

RF POWER OUTPUT MEASUREMENT

RF power output measurements can be made using an "Output Test Cable" which enables the attachment of an external load and RF Voltmeter to the VAPR generator. A schematic for a suggested "Output Test Cable" is shown in Figure 5.1. The output can be compared to the typical full and half power load curves listed in the following Technical Specifications section.

Note

Because the use of such a test cable with the VAPR generator is considered to be within the scope of certain proprietary intellectual property rights licensed to Mitek, each user is authorized to make and use with each of their VAPR generators a single test cable of this type, for the purpose of testing the RF output power of each such generator.

Any use of a user-made test cable as described or otherwise for the purpose of testing the RF output power of the VAPR generator shall not cause Mitek or its supplier of the VAPR System to be liable for direct, indirect consequential and/or special injury and/or damages, even if Mitek and/or such supplier have been advised of the possibility of such damages, arising from any cause whatsoever, including negligence.

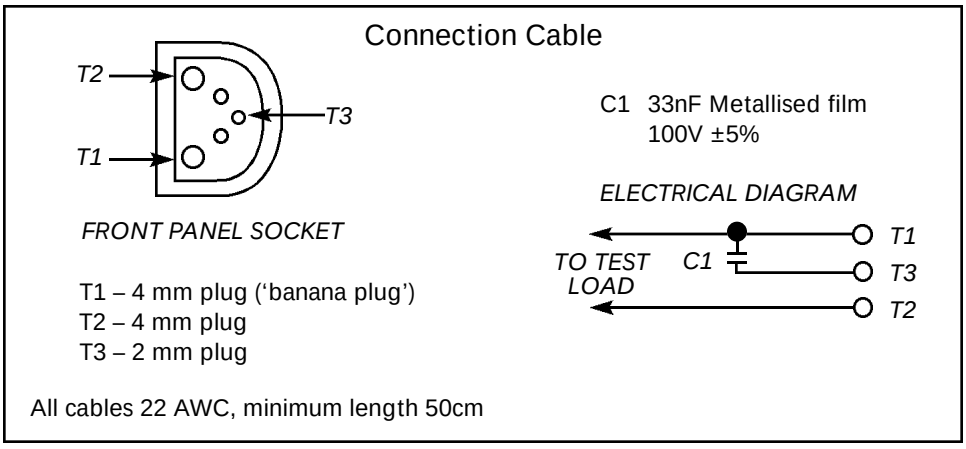


FIGURE 5.1

Note

The output specification is ±20% of the typical load curve value.

Caution

Mitek Products Inc. expressly recommends against attempting to make RF output power measurements by any other means than described in this manual.

Technical support in connection with end user corroboration of the published VAPR™ generator load curves can only be provided by Mitek on the condition that the user's measurement system corresponds to the test method layout depicted in Figure 5.2. This is the scheme adopted by Mitek for all product manufacture tests and has been found to be in accordance with the power measurement strategy for electrosurgical equipment employed by certified test agencies. Attempting to obtain an output power measurement by direct measure of voltage may give results that are inaccurate and unrepresentative of the system due to inducing earth loop currents or causing imbalance of the floating bipolar output stage.

Mitek recommends the use of the following equipment, or equivalents with at least commensurate specifications, when measuring RF output power:

EITHER	Fluke 8920A True RMS voltmeter
OR	Hewlett Packard 3403C True RMS voltmeter
	Pearson Model 411 Current monitor (0.1V/A)
	Arcol NHS200 series load resistors

When performing such measurements, Mitek recommends that the resistance loads should be of the noninductive type, minimum rating 200 watts. To verify output power against the published load curves, resistances of 68 ohm, 150 ohm and 1 kohm will be sufficient. Ensure that the generator has been correctly configured for the desired output modality prior to making measurements.

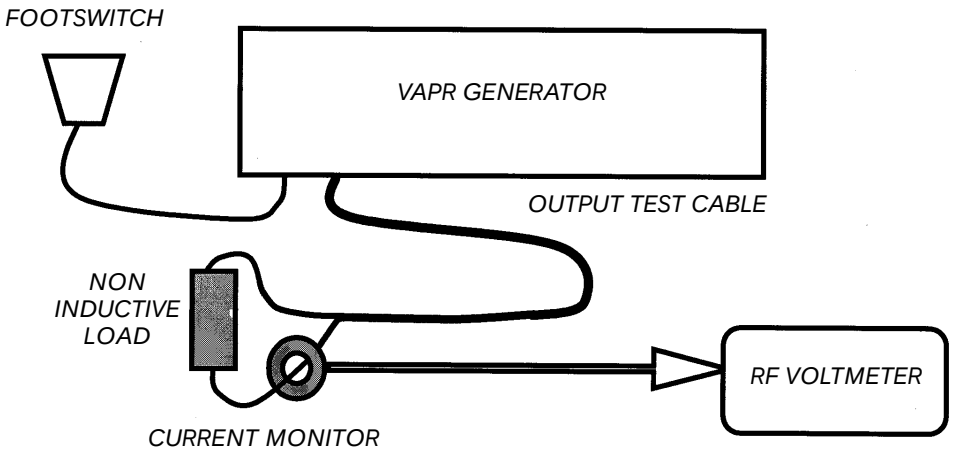


FIGURE 5.2

Caution

The practice of using an electrode as the power measurement connection medium is actively discouraged by Mitek Products Inc. Attempting to fashion a good electrical contact between the two poles of the small geometry electrode tip is fraught with difficulties and can lead to misleading results.

TECHNICAL SPECIFICATIONS

In this section, "typical" refers to a specification that is within ± 20% of a stated value at room temperature (25°C/ 77°F).

VAPR Electrode Specifications	
Overall Length:	5.7 - 8.9 in (14.5 - 22.5 cm)
Working Length:	3.7- 6.5 in (9.5 - 16.5 cm)
Shaft Diameter:	0.06 - 0.18 in (1.5 - 4.5 mm)
Shaft Bend Angle:	0 - 30°
Active Tip Orientation:	0 - 90°
Supplied Sterile and For Single-Use Only	
Sterilization Method:	Irradiation

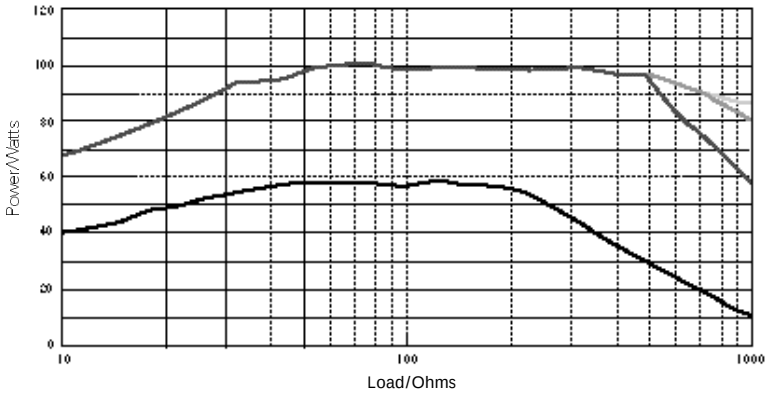
VAPR Handpiece and Cable Specifications	
Overall Length:	10.5 ft (3.2 m)
Sterilization Method:	Steam (134-136°C)
Supplied Non-Sterile	
20 x Reusable	

VAPR Generator Specifications	
Dimensions (H x W x D):	3.5 in x 16 in x 14.5 in (9 cm x 41 cm x 36.8 cm)
Weight:	12 lb. (5.6kg)
Transport and Storage Conditions	
Ambient Temperature Range:	32 to 122°F (0 to 50°C)
Relative Humidity:	10% to 100%, non condensing
Atmospheric Pressure:	500 to l060 millibars
Operating Conditions	
Ambient Temperature Range:	60 to 104°F (10 to 40°C)
Relative Humidity:	10% to 90%, non condensing
Atmospheric Pressure:	500 to l060 millibars
Power Supply	
Nominal Voltage:	115 Volts RMS or 240 Volts RMS 50/60Hz
Regulation Voltage:	90-270 Volts RMS
Operating Range:	nominal 110-120/220-240V RMS 50/60Hz
Inlet Fuses:	Time lag 5A (T5A)
Leakage Currents:	Within limits of Class BF equipment as per IEC 601-1
Alarm Volume:	Adjustable between 40dB (minimum) and 65dB (maximum) at 1m. This is an activation signal only.
Classification:	Class I ordinary equipment as per IEC 601-1.
Defibrillator Proof, Type BF equipment with isolated (F) applied part. Each of the electrode terminals of the Generator can withstand the effects of defibrillator discharge.	
Liquid Spillage as per IEC 601-2-2. The Generator enclosure will prevent reasonable amounts of liquid from interfering with the Generator's safe and satisfactory operation.	

Intermittent Operation

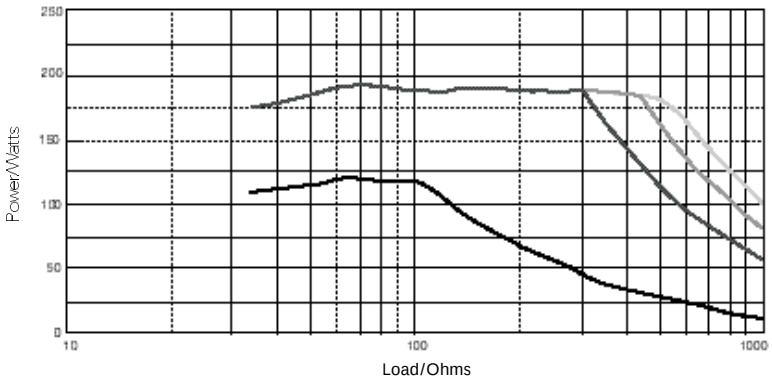
The Generator is cooled by natural convection. Under maximum power setting and rated load conditions the Generator is suitable for a 10 seconds on, 30 seconds off duty cycle for 1 hour.

HALF POWER (100W) LOAD CURVE



Desiccate at
Half Power 60W

FULL POWER (200W) LOAD CURVE



Note (1):
Desiccate
Full Power 120W
3A Limit prevents
10R measurement

Note (2):
Internal Limiting
10R Output

SECTION 2 - SAFETY INSPECTION RECORD

Model

Serial No.

Inventory No.

Date of Test

Performed by

Signature

Parameter	IEC 601-1	IEC 601-2-2	Limit(s)	Measured value
Protective Earth Impedance (PE)	18(f)	——	0.1 ohm	ohm
PE test current	18(f)	——	10 - 25A	A
Input voltage (V)	——	——	——	V
Input current: activating (I)	——	——	——	A
Input current: standby (IQ)	——	——	——	A
Input power (V x I)	7.1	——	440VA	VA
Earth leakage current (NC)	19.1(e)	——	500uA	uA
Earth leakage current (SFC)	19.2(a)	——	1mA	mA
Enclosure leakage current (NC)	19.1(d)	——	100uA	uA
Enclosure leakage current (SFC)	19.2(c)	——	500uA	uA
Patient leakage current (NC)	19.1(e)	——	100uA	uA
Patient leakage (mains on applied part)	19.2(b)	——	5mA	mA
RF leakage current	——	19.101(c)	100mA	mA
RF output power (150R, 200W, V3)	——	50.2	156 - 234W	W
RF output power (150R, 100W, V3)	——	50.2	80 - 120W	W
RF output power (150R, 60W, DES)	——	50.2	48 - 72W	W

NOTE

A copy of this table is located on the following page.

Model

Serial No.

Inventory No.

Date of Test

Performed by

Signature

Parameter	IEC 601-1	IEC 601-2-2	Limit(s)	Measured value
Protective Earth Impedance (PE)	18(f)	——	0.1 ohm	ohm
PE test current	18(f)	——	10 - 25A	A
Input voltage (V)	——	——	——	V
Input current: activating (I)	——	——	——	A
Input current: standby (IQ)	——	——	——	A
Input power (V x I)	7.1	——	440VA	VA
Earth leakage current (NC)	19.1(e)	——	500uA	uA
Earth leakage current (SFC)	19.2(a)	——	1mA	mA
Enclosure leakage current (NC)	19.1(d)	——	100uA	uA
Enclosure leakage current (SFC)	19.2(c)	——	500uA	uA
Patient leakage current (NC)	19.1(e)	——	100uA	uA
Patient leakage (mains on applied part)	19.2(b)	——	5mA	mA
RF leakage current	——	19.101(c)	100mA	mA
RF output power (150R, 200W, V3)	——	50.2	156 - 234W	W
RF output power (150R, 100W, V3)	——	50.2	80 - 120W	W
RF output power (150R, 60W, DES)	——	50.2	48 - 72W	W